

Message

From: Behl, Betsy [Behl.Betsy@epa.gov]
Sent: 8/4/2021 5:56:36 PM
To: Euling, Susan [Euling.Susan@epa.gov]; Jacobs, Brittany [jacobs.brittany@epa.gov]
CC: Miller, GregoryG [Miller.Gregory@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]
Subject: RE: FYI: ATSDR GenX inquiry

That is interesting. Thanks. The water sampling is interesting. The lack of detects in dust etc will be interesting when considering a RSC.

From: Euling, Susan <Euling.Susan@epa.gov>
Sent: Wednesday, August 4, 2021 11:07 AM
To: Jacobs, Brittany <jacobs.brittany@epa.gov>
Cc: Miller, GregoryG <Miller.Gregory@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>
Subject: FYI: ATSDR GenX inquiry

Some interesting information from Melanie Busey (at ATSDR) via Barbara who is the contact with ATSDDR:

I reached out to some colleagues on any monitoring activities ATSDR has planned for GenX:

- For the 8 Exposure Assessment sites ATSDR is working at, GenX was not included in any of the serum sample analysis. It was included as an analyte for urine, dust, and tap water. In looking at the results for the first six EA sites, GenX was not detected in any urine or dust samples and was detected in one tap water sample from one site. Not sure if this information is useful for you. For the last two sites we are still waiting on dust sample results from the laboratory but I would expect that there will be a similar picture there as well.
- For the upcoming Multi-Site Study, ATSDR is currently not including GenX as part of the analytical plan for PFAS at seven sites. [GenX contamination is very site specific (we don't have NC) and is detected in less than 3% of samples in NHANES]. ATSDR is planning to store some urine samples so this could be done in future if there is justification and a ppt/q level detection method.

Message

From: Behl, Betsy [Behl.Betsy@epa.gov]
Sent: 7/14/2020 8:44:23 PM
To: Strong, Jamie [Strong.Jamie@epa.gov]
CC: Miller, Gregory [Miller.Gregory@epa.gov]; Jacobs, Brittany [jacobs.brittany@epa.gov]
Subject: RE: Request for your review of revised GenX assessment

I agree. I think it an important aspect of science to recognize the things you do not know and to try to take those uncertainties into account. I would hope that for new chemicals we realize there is a balance between getting new and safer products into the market and applying appropriate cautions before licensing exposure for chemicals we really do not fully understand. I think the public thinks we are taking these uncertainties into consideration.

From: Strong, Jamie <Strong.Jamie@epa.gov>
Sent: Wednesday, July 08, 2020 8:26 AM
To: Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Miller, Gregory <Miller.Gregory@epa.gov>; Jacobs, Brittany <jacobs.brittany@epa.gov>
Subject: FW: Request for your review of revised GenX assessment
Importance: High

Betsy,

We will take care of 1 and 2. As for 3, I tend to disagree with Tala's statement that "this DB UF is not science-based". If anything OPPT's policy NOT to apply the DB UF absent any guidance or rationale seems not based in science.

Thanks,
Jamie

From: Henry, Tala <Henry.Tala@epa.gov>
Sent: Tuesday, July 07, 2020 4:24 PM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Cc: Henry, Tala <Henry.Tala@epa.gov>
Subject: RE: Request for your review of revised GenX assessment
Importance: High

Betsy/Jamie,

I reviewed, focusing on sections 5, 6, & 7. Todd Stedeford also took a quick look.

Only comments are:

- 1) This sentence at beginning of Section 5 is oddly worded, using 'effects' twice , adverse effects including...effects. The available studies indicate adverse effects including liver, developmental, hematological, and immune effects occur following exposures in the range of 0.5–1,000 mg/kg/day GenX chemicals.
- 2) The BW scaling approach, while 'not discouraged' is actually not recommended either; so suspect you will get comments on this from others. We appreciate the effort though, as it is an approach to reduce piling on uncertainty factors.
- 3) We also question the use of the Database Uncertainty factor; as you know our Office does not use this UF. Relatively speaking, this chemical has quite a lot of data, especially in the context of having gotten it through a program that has no data requirements. The write-up is fine, but doesn't provide a scientific basis for concluding that 10-fold adjustment would or would not account for the uncertainties identified (i.e., this DB UF is not science-based). This DB UF is inconsistent with promoting reductions in animal testing (another Agency priority).

Message

From: Miller, Gregory [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E889CDC40224A5484182092E4824FA7-GMILLE03]
Sent: 8/27/2020 6:36:31 PM
To: Strong, Jamie [Strong.Jamie@epa.gov]; Jacobs, Brittany [Jacobs.Brittany@epa.gov]
Subject: RE: Edits to GenX Charge for 2nd peer review after IO engagement

I made a couple edits. Looks good if this is the way we have to go.

From: Strong, Jamie <Strong.Jamie@epa.gov>
Sent: Thursday, August 27, 2020 7:13 AM
To: Jacobs, Brittany <jacobs.brittany@epa.gov>; Miller, Gregory <Miller.Gregory@epa.gov>
Subject: RE: Edits to GenX Charge for 2nd peer review after IO engagement

Greg I will fill you in. Ed, the sci int officer for OST, tried to convince us to change the SC to C UF to a 3 yesterday. He said our rationale for 10 is fine but to get though the IO we should change to 3 and ask peer reviewers if it should be higher. I pushed back quite hard.

From: Jacobs, Brittany <jacobs.brittany@epa.gov>
Sent: Wednesday, August 26, 2020 5:02 PM
To: Strong, Jamie <Strong.Jamie@epa.gov>; Miller, Gregory <Miller.Gregory@epa.gov>
Subject: Edits to GenX Charge for 2nd peer review after IO engagement

Hello,

Here is a first attempt at editing the SC to C UF like we discussed earlier. Please edit as you see fit. As a reminder, I am out tomorrow and Friday.

Britt

Message

From: Jacobs, Brittany [jacobs.brittany@epa.gov]
Sent: 10/15/2020 7:02:55 PM
To: Jacobs, Brittany [jacobs.brittany@epa.gov]; Miller, Gregory [Miller.Gregory@epa.gov]
Subject: Conversation with Jacobs, Brittany

Jacobs, Brittany 1:22 PM:

there's a version of GenX with Joyce comments?

Miller, Gregory 1:22 PM:

oh shit. you weren't on that email?

Jacobs, Brittany 1:23 PM:

I could have been but I have been getting a lot of emails recently

Miller, Gregory 1:23 PM:

i'm going to send her the 9/9 tech edited version with no ORD or Joyce comments. sound right? i still don't know what she's asking for. she want's the current draft

Jacobs, Brittany 1:24 PM:

I've been working on the one with ORD's comments

Jacobs, Brittany 1:24 PM:

been trying to make some edits to the language where it's easy to make the change

Jacobs, Brittany 1:24 PM:

I guess we could send both lol yeah I'm not sure what she is asking for either

Miller, Gregory 1:25 PM:

that's cool. is that "the current draft"? there seems to be this idea that we'd send the same version with UF10 around that we sent to ord and oppt

Jacobs, Brittany 1:25 PM:

I'm really not sure

Jacobs, Brittany 1:26 PM:

did Joyce respond to ORD's comments?

Miller, Gregory 1:26 PM:

hold on. let me dig

Miller, Gregory 2:21 PM:

i think my way is the way out. give it to them. they'd have to use NTP liver at least. more repro/dev data is coming. and when we pick it up again, we can decide about hte UFd for SDWA/HA or whatever.

Miller, Gregory 2:21 PM:

in the meantime, there's a RfD and everybody knows it'd be substandard because it has no UFd

Jacobs, Brittany 2:44 PM:

yeah, I'm really over this

Jacobs, Brittany 2:44 PM:

I think the other way is an intra-agency review and then we have all program offices except for OPPT agreeing that there needs to be a DB UF

Jacobs, Brittany 2:45 PM:

then we go to them and say 6 program offices think a DB UF is warranted while 1 does not

Jacobs, Brittany 2:45 PM:

then it'll be a matter of arguing 3 versus 10 but we will have more input on that

Miller, Gregory 2:45 PM:

it sounds like charlotte is locked in. she's not going to allow it out until we change the draft. she knows we'll get backing from other program offices there. that hurts her position

Jacobs, Brittany 2:46 PM:

yeah I mean if she isn't even going to let it go to intra-agency review then it should be a scientific integrity issue

Miller, Gregory 2:47 PM:

yup.

Miller, Gregory 2:48 PM:

i think it'd also be ok to sit on it for a month or so

Jacobs, Brittany 2:48 PM:

i wish we would've pushed for intra-agency review over external peer review

Jacobs, Brittany 2:48 PM:

but whatever

Jacobs, Brittany 2:48 PM:

yes

Jacobs, Brittany 2:48 PM:

or until this next fenton paper comes out

Jacobs, Brittany 2:48 PM:

justin's paper has just been accepted

Miller, Gregory 2:49 PM:

we can say that given the high level of concern, we want to wait for 2 new papers in this area that might help clarify the UFD need

Jacobs, Brittany 2:50 PM:

yeah that might be helpful

Jacobs, Brittany 2:50 PM:

I think it's going to sit anyway, guess we will see what happens on Monday

Miller, Gregory 2:51 PM:

what do we know about those studies?

Jacobs, Brittany 2:51 PM:

I'm also curious to see how Betsy reacts to all of this

Miller, Gregory 2:51 PM:

i'm sure betsy will want us to fight

Miller, Gregory 2:51 PM:

and would never consider passing it back to OPPT for completion

Jacobs, Brittany 2:51 PM:

I'm not sure they saw effects at doses similar to the liver

Jacobs, Brittany 2:52 PM:

but I can't be sure without modeling because they are repro/dev effects

Jacobs, Brittany 2:52 PM:

so I'm not sure what the PODs would look like

Jacobs, Brittany 2:52 PM: